

Claims:

1. High purity butoconazole nitrate of the formula (I) (chemical name: 1-[4-(4-chlorophenyl)-2-(2,6-dichlorophenylthio)-n-butyl]-imidazole nitrate) containing maximum 0.1 wt % of chemical impurities.

5 2. A compound according to claim 1, wherein at least 95 % of the particles of the substance are below 75 μm by diameter, whereas at least 99 % of the particles are below 250 μm by diameter.

10 3. A process for the preparation of 1-[4-(4-chlorophenyl)-2-(2,6-dichlorophenylthio)-n-butyl]-imidazole nitrate of the formula (I) defined in claim 1, said process comprising the steps

a) reacting 1-chloro-4-chlorophenyl-2-butanol with the imidazole of the formula (III) to yield a compound of the formula (IV).

b) reacting the compound formula of the (IV) obtained in step a), with thionyl chloride to yield a compound of the formula (V); and

15 c) reacting the compound of the formula (V) obtained in step b), with 2,6-dichlorothiophenol,

characterized in that

20 step a) is performed in a mixture of a water immiscible solvent and an aqueous solution of alkali metal hydroxide or carbonate in the presence of a phase transfer catalyst;

step b) is accomplished in 1,2-dichloroethane solvent in the presence of dimethylformamide, whereas 1-1.2 mol of thionyl chloride reagent is used based on the amount of the compound of the formula (IV); and

step c) is carried out without isolation of the product (VI); and

25 to the butoconazole (VI) being in solution as obtained in step c) nitric acid is added and the product is isolated as a nitrate salt.

4. A process according to claim 3, characterized in that the water immiscible solvent preferably is an aromatic hydrocarbon.

5. A process according to claim 4, characterized in that the aromatic hydrocarbon preferably is toluene.
6. A process according to claim 3, characterized in that the alkali metal hydroxide or carbonate preferably is sodium hydroxide or sodium carbonate.
- 5 7. A process according to claim 3, characterized in that step b), the thionyl chloride preferably is used in an amount of 1.1 mol.
8. A process for the preparation of a compound defined in claim 2, starting from a compound defined in claim 1, characterized in that the starting material is dissolved in a mixture of methanol and methyl isobutyl ketone of 1 – 1.5 : 1 ratio (v/v), this solution is
10 then added to methyl isobutyl ketone cooled to a temperature between 5 °C and -15 °C and the product obtained is isolated.
9. A process according the claim 8, characterized in that the cooling temperature is between -5 °C and -10 °C.
10. A process according the claim 8, characterized in that in the solvent for the starting
15 material the volume ratio of methanol/methyl isobutyl ketone preferably is 1.25 : 1.
11. A pharmaceutical composition comprising as active ingredient a compound defined in claim 2 in admixture with auxiliaries know per se.